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Ketorolac versus Magnesium Sulphate as an Adjuvant to Lidocaine in Intravenous Regional Anesthesia for Upper Limb Surgeries

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ABSTRACT

Background: intravenous regional anesthesia (IVRA) was first described almost a century ago by August Bier and has been used for the past 50 years. It is a safe anesthetic technique for upper or lower distal limb surgery.
Purpose: to compare the onset time of sensory blockade when adding ketorolac versus adding magnesium to the IVRA solution, and to compare the duration of postoperative analgesia.
Material and Methods: this is a randomized controlled trial in two groups. The study was performed in Ain Shams University Hospitals. Study period range was 1-2 years.
Results: there are 146 patients participated in our study, patients were allocated to two groups 73 patients in each group, a group of which received magnesium sulphate solution and the other received ketorolac solution.
Conclusion: we evaluated the effects of adding ketorolac and compared it to the effects of adding magnesium sulphate to the anesthetic solution used in IVRA and we found that magnesium sulphate addition can be of benefit in faster onset of sensory block in the operative limb. However, magnesium sulphate in the used concentration (10 ml MgSo4 10% in 40 ml solution) appeared to cause burning pain varying in intensity while injecting the anesthetic solution.
Keywords: *Magnesium Sulphate - Intravenous Regional Anesthesia - Upper Limb Surgeries – Ketorolac.*

INTRODUCTION

Analgesia and muscle relaxation are produced by the injection of an adequate local anesthetic solution into a distal peripheral vein of the extremity to be operated upon. The blood flow is prevented by a proximally applied pneumatic tourniquet. This technique is popular among the anesthetists around the world [(1)].

Many studies have suggested that IVRA is a safe and cost-effective technique to provide analgesia for upper limb surgeries with few side effects. However, its limitations are; lack of postoperative analgesia, tourniquet pain and time limit to surgical procedure [(2)].

There are a number of studies in which non-steroidal analgesics were added to local anesthetics to modify these limitations based on their local anesthetic properties. Going through a number of studies we could understand that ketorolac is among the commonest additives to IVRA solution [(3).]

The mechanism of the analgesic effect of magnesium is not clear, but interference with calcium channels and *N*-methyl-d-aspartate receptors seems to play an important role. Magnesium has been shown to be successful in decreasing pain associated with injection of propofol and rocuronium. Previous studies used magnesium for the treatment of chronic limb pain in IVRA and demonstrated that the addition of magnesium to lidocaine improves the quality of the block, extends the analgesia, and reduces the overall failure rate [(4)].

AIM OF THE STUDY

To compare the onset time of sensory blockade when adding ketorolac versus adding magnesium to the IVRA solution, and to compare the duration of postoperative analgesia.

PATIENTS AND METHODS

Type of study:

This is a randomized controlled trial in two groups.

Study Setting:

The study was performed in Ain Shams University Hospitals.

Study Period: From January 2017 to January 2018.

Study Population

- Inclusion criteria

All patients undergoing upper limb surgeries distal to the tourniquet level:

- Age 18-60 year.
- American Society of Anesthesiologists (ASA) I-II.

- Exclusion criteria

- Patients with known allergies to the study drugs.
- Patients with sickle cell anemia.
- Patients with Raynaud's disease.
- Patients who received any analgesic drug in the previous 24 h.

Sampling Method: Randomized controlled trial in two groups of 73 patients each admitted to Ain Shams

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University hospitals to undergo upper limb surgeries distal to tourniquet site.

Sample Size: With respect to sample size calculation, it was calculated using ps (version 3.0.43, Department of Biostatics, Vanderbilt University, located in Nashville, United States), Based upon the assumption that there is a difference in adding ketorolac or magnesium to lidocaine in IVRA and taking power 0.8 and alpha error 0.05, a minimum sample size of 146 patients was calculated. Finding difference in the effect of ketorolac and magnesium in IVRA is considered as primary endpoint of this study.

- **Ethical Considerations: The study was approved by the Ethics Board of Ain Shams University.** participants have been enrolled from September 2017 at Ain Shams University Hospitals and patients were informed a written consent and local ethical committee approval have been obtained before patient's allocation.
- **Study Procedures:** The patients were randomly assigned into 2 groups, Group M included *73* patient undergoing upper limb surgeries receiving *magnesium* with lidocaine in the anesthetic solution. Group K included *73* patient undergoing upper limb surgeries receiving *ketorolac* with lidocaine in the anesthetic solution.

Group M received anesthetic solution in the form of 10 ml Magnesium 10% (Eipico) added to 3 mg/kg lidocaine (Debocaine 2%- Arab Caps) and completed to 40 ml with normal saline.

Group K received anesthetic solution in the form of 30 mg ketorolac (Ketolac 30 mg/2 ml-Amirya Pharma Ind., Egypt) added to 3 mg/kg lidocaine (Debocaine 2%-Arab Caps) and completed to 40 ml with normal saline.

All patients received premedication with IV midazolam (Midathetic 5mg/1ml-Amoun) at 0.05 mg/kg given 30 min preoperatively.

Before performing IVRA the operative arm was elevated for 3 min and then exsanguinated with an Esmarch bandage, and a double pneumatic tourniquet was placed around the upper arm. The proximal cuff was inflated to about 100 mmHg above systolic blood pressure. Circulatory isolation of the arm was verified by inspection, absence of radial pulse, and loss of pulse oximetry tracing of the ipsilateral index finger.

The local anesthetic solution was injected slowly over 180 s. The sensory block was evaluated by pinprick test at 3-min intervals until 10 min after tourniquet inflation. Motor block was assessed by the inability to extend or flex wrist and fingers at 1-min intervals. After establishment of complete sensory and motor block, the distal cuff was inflated to the same pressure before deflation of the proximal one.

Tourniquet pain was evaluated using a Numerical Rating Score (NRS) (0 = no pain and 10 = worst pain) after cuff inflation in both groups. Recording of heart rate (HR) and mean arterial pressure (MAP) was done at baseline and 10, 20, and 30 min after distal tourniquet inflation. HR, MAP, and NRS was recorded again after cuff deflation and transfer to recovery room at 5, 30 and 60 min.

The tourniquet has not been deflated earlier than 30 min and has not been inflated for more than 1.5 h. At the end of surgery, the tourniquet deflation was carried out by cyclic deflation.

Postoperative pain was assessed by NRS after tourniquet release, 30 min and 60 min later. Cases with local anesthetic toxicity symptoms or signs was managed but discarded from the study.

Rescue analgesia during procedure was in the form of fentanyl 1mcg/kg in both groups, whenever NRS is above 4. Total dose of rescue analgesia was recorded for every patient in both groups.

Statistical Analysis: was performed using computer software statistical package for the social science (SPSS, version 20; SPSS Inc., Chicago, Illinois. USA).

Statistical Package: Description of quantitative (numerical) variables was performed in the form of mean ± SD. Description of qualitative (categorical) data was performed in the form of number of cases and percent. Error bars represent 95% confidence interval. ANOVA test and chi-square tests were used for comparison among different times in the same group in quantitative data. The significance level was set at p-value of 0.05 was considered significant and when less than 0.001 was considered highly significant.

RESULTS

Pre-operative complete sensory block:

Table (1): Comparison between groups as regard to the onset of complete sensory block (min.)

Pre-Op. Complete sensory block (min)	Group K (N=73)	Group M (N=73)	p-value	Sig.
Mean±SD	6.77±1.61	3.42±1.09	<0.001**	S
Range	4-9	2-6		

***p-value <0.001 HS*

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This table shows highly statistically significant difference between the two groups in which group M shows faster onset of sensory block.

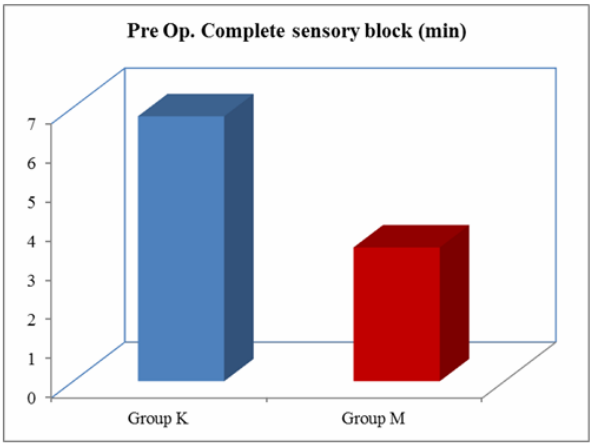

Fig. (1): Bar chart between groups according to pre-operative complete sensory block (min).

Intraoperative tourniquet pain:

Table (2): Comparison between groups as regard to NRS measuring tourniquet pain intra-operative

NRS in Operation	Group K (N=73)	Group M (N=73)	p-value	Sig.
At 0 min.				
Mean±SD	0.00±0.00	0.00±0.00	1.000	NS
Range	0-0	0-0		
At 10 min.				
Mean±SD	1.47±0.63	2.05±0.78	0.021*	S
Range	1-3	1-3		
At 20 min.				
Mean±SD	1.26±1.01	2.53±0.63	0.011*	S
Range	0-4	2-4		
At 30 min.				
Mean±SD	1.60±0.81	2.45±1.04	<0.001**	HS
Range	0-3	0-4		

**p-value <0.05 S; **p-value <0.001 HS; p-value >0.05 NS*

This table shows statistically significant difference between group M and group K in which patients in group M having higher incidence of tourniquet pain and discomfort especially after passing 30 minutes from inflating the tourniquet.

Intra-operative hemodynamics measurements:

Table (3): Comparison between groups as regard to intra-operative heart rate

Heart rate in Operation	Group K (N=73)	Group M (N=73)	p-value	Sig.
At 0 min.				
Mean±SD	81.23±4.11	80.63±3.89	0.365	NS
Range	73-88	73-88		
At 10 min.				
Mean±SD	80.10±3.46	79.16±5.04	0.195	NS
Range	71-86	68-86		
At 20 min.				
Mean±SD	79.36±3.02	79.15±5.32	0.774	NS
Range	72-85	67-86		
At 30 min.				
Mean±SD	79.07±3.30	79.08±6.07	0.986	NS
Range	71-86	62-85		

P-value >0.05 NS

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This table shows no statistically significant difference between groups according to heart rate measurements intra-operatively.

Table (4): Comparison between groups as regard to intra-operative mean arterial pressure

MAP in Operation	Group K (N=73)	Group M (N=73)	p-value	Sig.
At 0 min.				
Mean±SD	95.63±4.16	93.88±3.16	0.065	NS
Range	90-103	90-100		
At 10 min.				
Mean±SD	94.32±4.45	94.34±5.21	0.973	NS
Range	82-100	83-104		
At 20 min.				
Mean±SD	94.47±3.43	96.60±3.67	0.310	NS
Range	88-102	90-103		
At 30 min.				
Mean±SD	93.41±4.18	96.68±3.45	0.061	NS
Range	80-100	90-102		

P-value >0.05 NS

This table shows no statistically significant difference between the two groups according to their intra-operative mean arterial pressure.

Post-operative pain assessment:

Table (5): Comparison between groups as regard to NRS score for post-operative pain

NRS in post operation	Group K (N=73)	Group M (N=73)	p-value	Sig.
After 5 min.				
Mean±SD	0.71±0.77	1.92±1.01	<0.001**	HS
Range	0-2	0-4		
After 30 min.				
Mean±SD	1.53±0.73	3.53±1.28	<0.001**	HS
Range	1-3	1-5		
After 60 min.				
Mean±SD	1.59±0.70	2.85±0.81	<0.001**	HS
Range	1-3	2-4		

***p-value <0.001 HS*

This table shows highly statistically significant difference between groups according to NRS pain score post-operatively with p-value less than 0.001 where NRS was higher in group M.

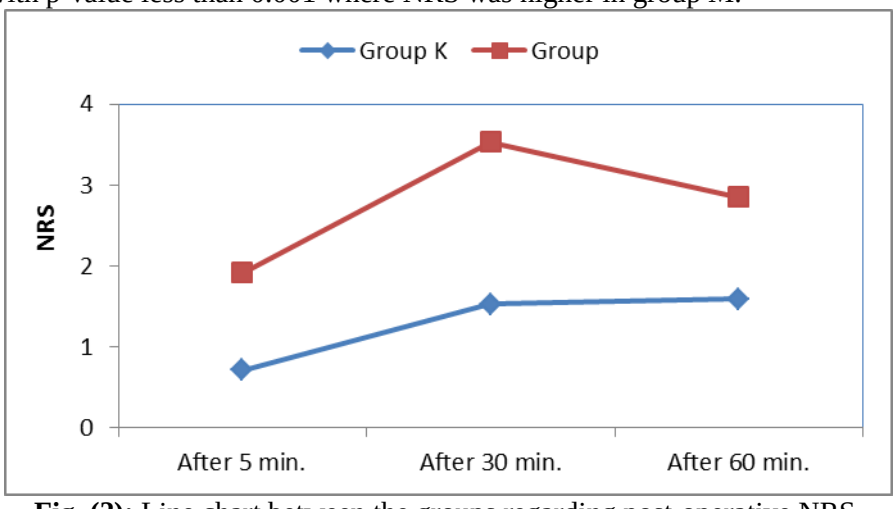

Fig. (2): Line chart between the groups regarding post-operative NRS.

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Post-operative hemodynamics

Table (6): Comparison between the two groups heart rate measurements post-operatively

Heart rate in post operation	Group K (N=73)	Group M (N=73)	p-value	Sig.
After 5 min.				
Mean±SD	77.67±3.00	79.00±5.29	0.064	NS
Range	73-83	68-88		
After 30 min.				
Mean±SD	77.96±4.22	84.18±6.43	<0.001**	HS
Range	73-87	73-95		
After 60 min.				
Mean±SD	78.08±5.17	83.29±6.54	<0.001**	HS
Range	70-90	67-90		

***p-value <0.001 HS*

This table shows statistically significant difference in post-operative heart rate measurements especially after passing 30 minutes where it showed higher readings for patients in group M.

Table (7): Comparison between groups according to post-operative measurements of mean arterial pressure

MAP in post operation	Group K (N=73)	Group M (N=73)	p-value	Sig.
After 5 min.				
Mean±SD	92.33±2.08	94.41±2.93	0.077	NS
Range	89-96	90-101		
After 30 min.				
Mean±SD	91.86±2.81	99.30±4.69	<0.001**	HS
Range	88-98	90-105		
After 60 min.				
Mean±SD	90.45±2.32	97.71±4.34	<0.001**	HS
Range	87-95	92-108		

***p-value <0.001 HS; p-value >0.05 NS*

This table shows statistically significant difference in post-operative blood pressure measurements especially after passing 30 minutes showing relation with heart rate and pain score measurements.

Analgesics administration

1.Intra-operative:

Table (8): Comparison showing the number of patients who needed intra-operative analgesics in each group

Intraoperative analgesics	Group K (N=73)	Group M (N=73)	p-value	Sig.
No	68 (93.2%)	58 (79.5%)	0.016*	S
Yes	5 (6.8%)	15 (20.5%)		

**p-value <0.05 S*

This table shows statistically significant difference between the number of patients who needed intra-operative analgesics in the form of intravenous fentanyl due to tourniquet pain showing increased number of patients in group M.

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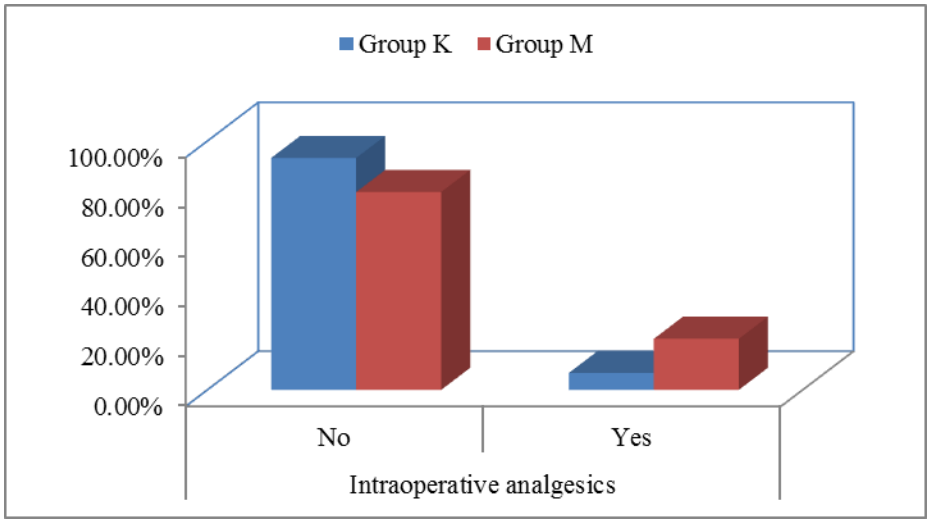

Fig. (3): Bar chart between groups according to intraoperative analgesics.

Table (9): Comparison between groups according to the dose of given intra-operative analgesics in each group

Intraoperative total analgesics	Group K (N=73)	Group M (N=73)	p-value	Sig.
Mean±SD	73.01±4.47	78.33±2.44	<0.001**	HS

**p-value <0.05 S*

This table shows statistically significant difference in the average dose given to each patient who needed analgesics showing increased dose with group M patients.

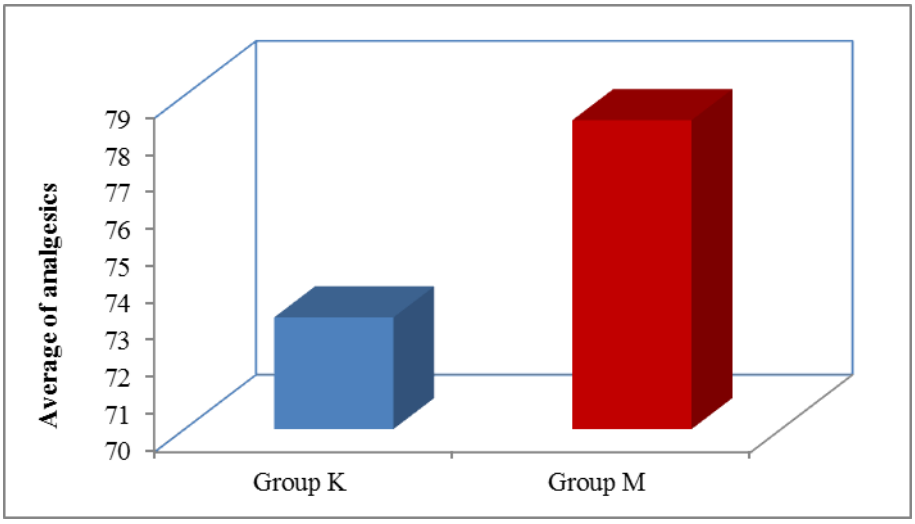

Fig. (4): Bar chart between groups according to intraoperative analgesics.

2. Post-operative

Table (10): Comparison between groups as regard to post-operative analgesics administration

Post-operative analgesics & events	Group K (N=73)	Group M (N=73)	p-value	Sig.
No	58 (79.5%)	20 (27.4%)	<0.001**	HS
Yes	15 (20.5%)	53 (72.6%)		

***p-value <0.001 HS*

This table shows highly statistically significant difference between groups according to the need for post-operative analgesics showing higher number of patients in group M needing analgesics.

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DISCUSSION

IVRA is suitable for operations of the distal extremities, in situations where it is safe and easy to apply an occlusive tourniquet. It is mainly used for surgical procedures of the upper extremity, but it can also be used for procedures involving the lower extremity. The primary advantages of IVRA are its simplicity, reliability, and cost effectiveness. It is a regional anesthetic technique that is easy to perform, with success rates varying between 94% and 98%. The rapid recovery of function makes this technique ideally suited for surgeries performed in an ambulatory setting [(5)].

Various adjuncts added to LA have been investigated in an attempt to improve the quality of IVRA, including opioids, muscle relaxants, nonsteroidal anti-inflammatory drugs (NSAIDs), clonidine, potassium, and alkalizing agents. A systematic review of IVRA adjuncts performed by Choyce and Peng [(5)] suggested that NSAIDs were most useful for improving postoperative analgesia after IVRA. New studies continue to be published in the search for an ideal adjunct**.**

Magnesium has been shown to be successful in decreasing pain associated with injection of propofol and rocuronium. Previous studies used magnesium for the treatment of chronic limb pain in IVRA and demonstrated that the addition of magnesium to lidocaine improves the quality of the block, extends the analgesia, and reduces the overall failure rate [(4)].

In our randomized controlled study, we compared the effect of adding Ketolorac versus adding Magnesium Sulphate to Lidocaine for IVRA. The results showed significantly lower intraoperative and postoperative NRS pain score within Ketorolac group as well as significantly less analgesic requirements compared to Magnesium sulphate group. There were no statistically significant differences regarding intraoperative haemodynamic changes between the two groups. However, magnesium sulphate showed faster onset for sensory block as compared to ketorolac.

In a recent study by ***Seyfi et al.*** [(6)] 40 patients undergoing elective upper limb were selected and randomly divided into two groups. The first group of 20 patients received 200 mg of lidocaine, and the second group, 200 mg of lidocaine with 20 mg of ketorolac. The onset of sensory block, onset of tourniquet pain, the onset of pain after opening the tourniquet, score of postoperative pain and analgesic prescription in the first 24 hours, during 1, 6, 12 and 24 hours were studied. They showed that in the ketorolac group, the onset of pain after inflating the tourniquet was significantly longer than lidocaine group ($p<0.001$). The mean postoperative pain score during the first 24 hours after surgery in the ketorolac group was significantly lower than lidocaine group ($p<0.001$). The average number of analgesia prescription during the 24 hours after operation was significantly lower in ketorolac group than lidocaine group ($p<0.001$) [(6)].

Similar results obtained by ***Hosam et al.*** [(7)] highlighting the favorable effect of adding Ketorolac to Lidocaine on postoperative pain control. In their study A total of 78 patients scheduled for hand and forearm surgery were randomly assigned to one of three groups; the control group (Patients received 3mg/kg Lidocaine made with 40ml normal saline), Melatonin group (Patients received 3mg/kg Lidocaine made with 40ml normal saline plus oral Melatonin 0.15mg/kg one hour preoperatively) and Ketorolac group (Patients received 3mg/kg Lidocaine made with 40ml normal saline with an adjuvant Ketorolac 20mg). Tourniquet pain was measured every 10mins. Need for intra- operative opioids were recorded.Their results showed that Intra-operative pain score was significantly lower while the time of first request of analgesia was significantly longer in the Melatonin and Ketorolac groups than the control group. 24h postoperative analgesic consumption was higher in the Melatonin and the control group than Ketorolac group. Patient and Surgeon satisfaction were significantly higher with Melatonin and Ketorolac than in the control group [(7)].

An earlier study by ***Jankovic et al.*** [(8)] demonstrated the similar effects of using Ketorolac as an adjunct to IVRA. Their study involved 45 patients undergoing ambulatory hand surgery. They were randomly allocated into three groups: Group L, Group LK and Group LDK. Group L received 3 mg·kg-1 lidocaine; Group LK received 3 mg·kg-1 lidocaine + 30 mg ketorolac; and Group LDK received 3 mg·kg-1 lidocaine for IVRA + 8 mg dexamethasone + 30 mg ketorolac for IVRA using a 40 mL solution. Sensory and motor block onset and recovery times were recorded. Tourniquet pain and pain at the operative site were assessed by a visual analog scale. In the first 24 h after surgery, opioid requirements and total analgesic consumption, including side effects, were noted. Patients in Groups LK and LDK required less alfentanyl for control of intraoperative and early postoperative pain. Further, patients in Groups LK and LDK reported significantly lower pain scores compared to those in Group L ($P<0.001$). Patients in Groups LK and LDK required fewer postoperative ketorolac tablets (2.2±1.6 and 1.3±0.6 tablets, respectively) in the first 24 h after surgery and had significantly longer periods during which they required no analgesics (524 min and 566 min, respectively)

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compared to those in Group L (3.8±1.3 tablets; 122 min, P<0.001) [8].

In another study using different NSAID, ***Yurtlu et al.*** [9] evaluated the effects of dexketoprofen as an adjunct to lidocaine in intravenous regional anesthesia (IVRA) or as a supplemental intravenous analgesic. Patients scheduled for elective hand or forearm soft-tissue surgery were randomly divided into three groups. All 45 patients received 0.5% lidocaine as IVRA. Dexketoprofen was given either IV or added into the IVRA solution and the control group received an equal volume of saline both IV and as part of the IVRA. The times of sensory and motor block onset, recovery time and postoperative analgesic consumption were recorded. Compared with controls, the addition of dexketoprofen to the IVRA solution resulted in more rapid onset of sensory and motor block, longer recovery time, decreased intra- and postoperative pain scores and decreased paracetamol use [9].

On the other hand, several studies were performed to investigate the effect of adding Magnesium sulphate as an adjunct in IVRA. The mechanism of the analgesic effect of magnesium is not clear, but interference with calcium channels and N-methyl-d- aspartate receptors seems to play an important role.

Turan et al. [10] conducted their study to evaluate the effects of magnesium, when added to lidocaine for IVRA on tourniquet pain. Thirty patients undergoing elective hand surgery during IVRA were randomly assigned to two groups. IVRA was achieved with 10 mL of saline plus 3 mg/kg lidocaine 0.5% diluted with saline to a total of 40 mL in group C or with 10 mL of 15% magnesium sulfate (12.4 mmol) plus 3 mg/kg lidocaine 0.5% diluted with saline to a total of 40 mL in group M. Injection pain, sensory and motor block onset and recovery time, tourniquet pain, and anesthesia quality were noted. Patients were instructed to receive 75 mg of IM diclofenac when the visual analog scale (VAS) score was 4, and analgesic requirements were recorded.

Their results showed that VAS scores of tourniquets pain was lower in group M at15,20,30,40, and 50 min (P<0.001). Anesthesia quality, as determined by the anesthesiologist and surgeon, was better in group M (P<0.05). Time to the first postoperative analgesic request in group C was 95 ± 29 min and in group M was 155 ± 38 min (P<0.05). Postoperative VAS scores were higher for the first postoperative 6 hours in group C (P<0.05). Diclofenac consumption was significantly less in group M (50 ± 35 mg) when compared with group C (130 ± 55 mg) (P<0.05) [10].

They also reported that the side effect seen with magnesium injection pain; however, it was diminished with the lidocaine dose and concentration they used.

Different studies were conducted to compare the effect of Magnesium with other additives showed variable results.

A study by ***El-Tahawy et al.*** [11] compared the use of dexmedetomidine with that of magnesium sulfate as an adjuvant for IVRA as regards onset and duration of sensory and motor blocks, quality of anesthesia, intraoperative–postoperative hemodynamic variables, and intraoperative and postoperative pain.

In their study sixty patients scheduled for upper hand or forearm surgery were randomly divided into two groups, comprising 30 patients each. Group D received dexmedetomidine at 0.5 μg/kg diluted with saline to 20 ml in addition to 20 ml of 1% lidocaine to reach a total volume of 40 ml, whereas group M received 5 ml of 20% magnesium sulfate and 15 ml saline added to 20 ml of 1% lidocaine to reach a total volume of 40 ml.

Although there was no statistically significant difference observed between dexmedetomidine and magnesium sulfate as regards sensory block onset time and motor block onset time (P = 0.102 and 0.206, respectively) as well as intraoperative analgesic requirements (P = 0.76). However, dexmedetomidine showed more favorable hemodynamic variables and less tourniquet pain [11].

Another recent study by ***Kaur et al.*** [12] compared the efficacy of clonidine versus MgSO4 as an adjunct to lignocaine in IVRA for postoperative analgesia and to compare their side effect profile. Forty adult patients were included. Patients were assigned into two groups; Group 1 (n = 20) received 3 mg/kg of 2% lignocaine + 50% MgSO4 1.5 g diluted with normal saline to 40 ml. Group 2 (n = 20) received 3 mg/kg of 2% lignocaine + clonidine 150 μg diluted with normal saline to 40 ml. Pain score, time to first rescue analgesic (TTFA), total number of rescue analgesics required, and the side effects of the two drugs were compared for 24 h postoperatively.

They concluded that the mean TTFA was significantly longer in Group 1 (193.9 ± 38.4 min) than in Group 2 (169.5 ± 33.3 min); P < 0.05. The mean number of rescue analgesics required was 1.6 ± 0.7 in Group 1 as compared to 2.1 ± 0.8 in Group 2 (P < 0.05). More serious side effects such as hypotension and bradycardia were noted with

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clonidine, although all patients experienced transient pain during intravenous injection of $MgSO_4$ [(12)].

To be mentioned, magnesium sulphate anesthetic injections showed mild to intense burning sensation while injecting in most of the patients, but the pain was transient and got relieved by itself within few minutes. This event has been noticed by ***Kaur et al.*** [(12)].

The exact etiology of pain on IV injection of $MgSO_4$is unknown but has been attributed to acidity of the solution.

Also, we noticed in a fraction of the patients injected with the magnesium sulphate solution that immediately after deflating the tourniquet some patients suffered from drowsiness, light headedness and sometimes brief pass out. We don't know whether this is related to magnesium sulphate, the local anesthetics, or other cause.

We think these events should be more investigated in other studies to know the prevalence and cause of these symptoms if they happen to be significant.

CONCLUSION

In conclusion, we evaluated the effects of adding ketorolac and compared it to the effects of adding magnesium sulphate to the anesthetic solution used in IVRA and we found that magnesium sulphate addition can be of benefit in faster onset of sensory block in the operative limb. Although both groups appeared to have no significant difference regarding hemodynamic measurements intra-operatively, patients injected with anesthetic solution containing 30 mg ketorolac showed better tolerance to tourniquet pain and post-operative pain. So, we concluded that although magnesium sulphate addition had the upper hand regarding the onset of sensory block, ketorolac addition showed better overall quality of anesthesia due to its intra-operative and post-operative analgesic effect.

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